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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/531,375	03/21/00	HALLER	A 7682-049

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PENNIE AND EDMONDS
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EXAMINER	
SALIMI, A	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 11/07/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/531,375	Haller et al
Examiner	**Art Unit**
ALI R. SALIMI	1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *Three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Sep 7, 2001* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above, claim(s) *7-16* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-6* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *7*

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

Claims 1-16 are pending.

Submitted Information Disclosure Statement (I.D.S) is noted.

Notice of draftsperson's patent drawing review (PTO 948) is enclosed.

Election/Restriction

Applicant's election with traverse of Group I (Claims 1-6) in Paper No. 8 is acknowledged. However, since no argument was set forth by the applicant the election was treated as an Election **without** traverse. Hence, claims 7-16 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected Groups. Claims 1-6 are considered.

Applicants are reminded to cancel the claims to the non elected claims.

Claim Rejections - 35 USC § 112

Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague, indefinite, and very confusing. The intended chimeric virus is ill defined. Normally for a chimeric of anything there are two distinct of something that form the chimera, and

the limitations are present that would defined their intended use. The claim as written now is very confusing the boundaries of chimera is not defined, and its intended function is not present. The metes and bounds of the intended heterologous sequences are not defined. It is not clear what genes are being substituted added or deleted? It is not clear whether the invention is directed to a chimeric vector, which means genes from two different types of virus are fused as to form a virus that is capable of expressing a foreign gene, or a general parainfluenza expression vector wherein the vector is capable of expressing foreign antigens. If a chimeric virus is intended then the claim should clearly indicate which genes of the two intended viruses form the chimeric virus. And if a bovine parainfluenza virus is intended to be utilized as a general expression vector then the claim should clearly indicate which genes are being deleted and where a heterologous gene is being inserted. Moreover, the claim is confusing for recitation of "comprising backbone... sequences", what are these sequences? What are the genes that form the "backbone"? This affects the dependent claims.

In addition, claims 1, 2, 4, and 5 are indefinite for recitation of the term "derived". The term "derived" is not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. In the instant case, the definition of derivation has many meaning, therefore, the claim is considered as indefinite.

Claims 2, and 5 are vague and indefinite, the intended heterologous sequence are not defined. This affects claims 3, and 4.

Claim 6 is indefinite for recitation of "mutations or modifications", the intended "mutations or modifications" are not defined, moreover, the term "modification" is a relative term subject to varied interpretations. What is/are the mutations that causes the formulation to be expressing attenuated phenotype(s)? Moreover, the claim is indefinite for recitation of "enhanced antigenicity", this is a relative terminology, how is the "enhancement" determined?

Claim Rejections - 35 USC § 112

Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for bovine parainfluenza type 3 (bPIV3) having its surface glycoproteins HN and F genes being substituted with HN and F glycoproteins of human parainfluenza virus type 3 (hPIV3) , forming a chimeric bPIV3/hPIV3 virus that is utilized in induction of immune response (antibodies only) which happens to exhibit temperature attenuating characteristics, does not reasonably provide enablement for all types of chimeric viruses with bPIV3 "backbone" wherein all types of genes from all types of viruses would induce protective response (vaccine) or exhibit "enhanced antigenicity" with any and all types of modifications. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. The specification

discloses substitutions of surface glycoproteins HN and F of bPIV3 with HN and F glycoproteins of human parainfluenza virus type 3 capable if inducing antibodies. The specification does not provide teaching with regard to the vaccine development eliminating any viral infection including parainfluenza virus. Applicants are reminded that the field of vaccine development is extremely unpracticable. The teaching of the specification is deficient in providing complete protection against any virus, there are no challenge study present that would show complete protection against any virus. The scope of the claims read on vaccine for HIV and many other viruses, however, the state of the art does not recognize such assertions and absent clear teaching undue experimentations would be required. The scope of the claims are directed to all types of chimeric vaccines, Applicants have general statements regarding the vaccine composition and an induction of protective response. However with regard to an unpredictable field, this does not constitute an adequate disclosure. See Fiers v. Revel (25USPQ2d 1601 at 1606; and also decision by the Federal Circuit with regard to the enablement issues see Genentech Inc. v. Novo Nordisk A/S, 42 USPQ2d 1001-1007). For example, the CAFC stated that "It is the specification, not the knowledge of one skilled in the art that must supply the novel aspects of an invention in order to constitute enablement." (See page 1005 of the decision). In the instant case the specification does not teach or provide any guidance for development of a vaccine for any virus. This means that the disclosure must adequately guide the art worker to determine, without undue experimentation. The applicant can not rely on the knowledge of those skilled in the art to enable the claims without providing adequate teaching. Therefore, considering large quantity of experimentation

needed, the unpredictability of the field, the state of the art, and breadth of the claims, it is concluded that undue experimentation would be required to enable the intended claim. Many of these factors have been summarized *In re Wands, 858 F.2d 731, USPQ2d 1400 (Fed. Cir. 1988)*.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Murphy et al (WO 98/53078).

The above cited patent meets the limitations of the claimed invention. The above cited patent clearly taught that a bovine parainfluenza virus may be modified to comprise heterologous genes including glycoproteins that can be substituted from human PIVs that would induce immunogenic response (see page 37, lines 2-10). In addition, they taught various chimeric parainfluenza viruses (PIV) wherein modified PIV comprises of human PIV genomic and non-human PIV sequence such as human and bovine (see bridging paragraph 39-40). The claims of the above cited patent clearly teach and anticipates the applicants invention (see all the claims especially claims 1-9). The product disclosed in the above cited patent appears to be identical or

so similar that is indistinguishable from the product claimed by the applicants. Applicants are reminded that the Patent Office does not have facilities to perform physical comparisons between the claimed product and similar prior art products. Hence, the disclosure of the above cited patent anticipates the claimed invention. Applicants are reminded that the intended use of a product does not carry patentable weight.

The following articles are not prior art and are cited as of interest only:

Schmidt et al. Journal of Virology, Oct. 2000, Vol. 74, No. 19, pp. 8922-8929.

Skiadopoulos et al. Journal of Virology, Nov. 2001, Vol. 75, No. 21, pp. 10498-10504.

WO 01/04320 A1 (front page only), please pay special attention to the priority data of (July 9, 1999).

No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ali R. Salimi whose telephone number is (703) 305-7136. The examiner can normally be reached on Monday-Friday from 9:00 Am to 6:00 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for this Group is (703) 305-3014, or (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Ali R. Salimi

11/2/2001